

## Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

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## Appendix C. Clinical Trial Efficacy Data for Daily, Oral Tenofovir Disoproxil Fumarate/Emtricitabine as Pre-Exposure Prophylaxis

Study <sup>a</sup>	Population	Regimen	Efficacy (95% CI)	Percentage of Participants with Detectable Plasma Levels of TFV
Partners PrEP $(n = 4,758)^1$	Serodiscordant couples in Kenya and Uganda	TDF/FTC	75% (55% to 87%)	82% <sup>b</sup>
	n = 1,579 randomized to receive TDF/FTC			
CDC TDF2 $(n = 1,215)^2$	Heterosexual men and women in Botswana	TDF/FTC	63% (22% to 83%)	<b>79%</b>
Fem-PrEP (n = 2,056) <sup>3</sup>	Heterosexual women in South Africa, Kenya, and Tanzania	TDF/FTC	No effect	24%
<b>VOICE</b> (n = 5,029) <sup>4</sup>	Heterosexual women in South Africa, Uganda, and Zimbabwe	TDF/FTC	No effect	29%
	n = 1,003 randomized to receive TDF/FTC			

<sup>&</sup>lt;sup>a</sup> The data in this table are from studies that included heterosexual women.

Key: CI = confidence interval; FTC = emtricitabine; PrEP = pre=exposure prophylaxis TDF = tenofovir disoproxil fumarate; TFV = tenofovir

## References

- 1. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med.* 2012;367(5):399-410. Available at: <a href="http://www.ncbi.nlm.nih.gov/pubmed/22784037">http://www.ncbi.nlm.nih.gov/pubmed/22784037</a>.
- 2. Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med*. 2012. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22784038.
- 3. Van Damme L, Corneli A, Ahmed K, et al. Preexposure prophylaxis for HIV infection among African women. *N Engl J Med*. 2012;367(5):411-22. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22784040.
- 4. Donnell D, Baeten JM, Bumpus NN, et al. HIV protective efficacy and correlates of tenofovir blood concentrations in a clinical trial of PrEP for HIV prevention. *J Acquir Immune Defic Syndr*. 2014;66(3):340-348. Available at: <a href="https://www.ncbi.nlm.nih.gov/pubmed/24784763">https://www.ncbi.nlm.nih.gov/pubmed/24784763</a>.

Among the patients who achieved detectable plasma levels of TFV, the efficacy estimate for daily TDF/FTC was 91% (95% CI, 47% to 98%).4